UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

KENNETH DOWNING, individually and on behalf of all others similarly situated, Plaintiff, v. ANAVEX LIFE SCIENCES CORPORATION and CHRISTOPHER U. MISSLING, Defendants.	Case No. 1:24-cv-03529-CM

DEFENDANTS' MEMORANDUM OF LAW
IN SUPPORT OF THEIR
MOTION TO DISMISS THE COMPLAINT

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Anavex	Anavex Life Sciences Corporation
Class Period	June 21, 2021 to January 1, 2024, inclusive
CGI-I	Clinical Global Impression of Improvement Scale
FDA	U.S. Food and Drug Administration
MMRM	Mixed-effects models for repeated measures
PSLRA	Private Securities Litigation Reform Act of 1995
RSBQ	Rett Syndrome Behavioural Questionnaire
RSBQ AUC	Rett Syndrome Behavioural Questionnaire (RSBQ) Area Under the Curve (AUC)

PRELIMINARY STATEMENT

This is a prototypical strike suit. It is a copycat of another class action lawsuit, filed mere days before the closing of the PSLRA period as part of an (unsuccessful) effort to cause Mr. Downing to be appointed as lead plaintiff. The Complaint's inadequacies are striking and numerous, revealing seemingly no effort to undertake basic due diligence or develop the allegations in a manner that could come close to surviving dismissal, let alone satisfy the heightened standards applicable to securities fraud lawsuits. Indeed, the central premise of the suit—that the endpoints for the Excellence study were not revealed until the end of the Class Period—is demonstrably false, as such matters were disclosed, directly and explicitly, on multiple occasions. It is no surprise, then, that the allegations overall lack particularity and fail to muster anything more than boilerplate to support scienter—there is nothing for Plaintiff to have pled in support of such unfounded and unsupportable claims.

Plaintiff alleges that Defendant Anavex Life Sciences Corporation ("Anavex" or the "Company") and its CEO, Dr. Christopher U. Missling, misled investors because the "endpoints" in two studies changed between the study announcement and release of the results. What Plaintiff fails to allege, however, is fraud. As explained below, beyond a handful of conclusory sentences, there are no allegations to support that Defendants acted with fraudulent intent. The absence of even a passing effort to meet this fundamental pleading burden is alone fatal to the case. And clear intra-Class Period disclosures of the allegedly non-disclosed facts further illustrate a lack of investigation and support for these claims. Such disclosure undermines the elements of falsity and loss causation. It is therefore unsurprising that the allegations as to the purportedly misleading statements also lack particularity and in some cases are demonstrably untrue. Finally, indicative of the purely tactical nature of this lawsuit, many of the alleged misstatements are clearly time-

barred and appear to have been included solely to aid in getting Mr. Downing appointed as lead plaintiff.

For all of these reasons the Complaint should be dismissed with prejudice.

BACKGROUND[1]

I. Anavex and Its Rett Syndrome Studies

Anavex is a biopharmaceutical company working to develop treatments for certain nervous system diseases, including ANAVEX 2-73. Compl. ¶ 2.[2] Anavex engaged in several clinical trials for this drug, including a U.S. Phase 2 study (results announced December 2020); the Avatar study (results announced February 1, 2022); and the Excellence study (results announced January 2, 2024). Compl. ¶¶ 6-7, 56. These studies each had "endpoints," i.e., measures used to determine success relative to Rett Syndrome. Endpoints for Rett Syndrome include the Rett Syndrome Behaviour Questionnaire ("RSBQ"), which is measured by the patient's caregiver, and the Clinical Global Impression Improvement Scale ("CGI-I"), which is physician measured. Compl. ¶ 29. As is typical in the biopharmaceutical industry, each study was double-blinded (i.e., the Company did not know who received treatment and who received placebos). Ex. 1 (2023 Form 10-K) at 10.

A. The U.S. Phase 2 Study (ANAVEX®2-73-RS-001)

Anavex commenced a U.S.-Based Phase 2 trial in March 2019. See Ex. 2 (2022 Form 10-K) at 9. The primary endpoint of the trial was safety; secondary efficacy endpoints were measured

[1] This section accepts as true the non-conclusory allegations in the Complaint and cites materials the Court can properly consider, including "statements or documents incorporated into the complaint by reference, legally required public disclosure documents filed with the SEC, and documents possessed by or known to the plaintiff and upon which it relied in bringing the suit." ATSI Commc'ns, Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 98 (2d Cir. 2007). Such materials are provided as exhibits to the Declaration of Theodore L. Kornobis, referred to herein as "Ex. __".

[2] As one example of demonstrably false "factual" allegations, Plaintiff mistakenly alleges Anavex is a Delaware corporation (Compl. ¶ 16) when it is in fact incorporated in Nevada. Ex. 1.

using RSBQ and CGI-I. Id. On December 15, 2020, Anavex announced that the U.S.-Based Phase 2 trial met the primary and secondary endpoints. Id. Approximately six months later, Anavex announced further results from the same trial; specifically, that predictive biomarker data correlated with the improvements seen in the two primary clinical efficacy endpoints of RSBQ and CGI-I. Ex. 3 (June 21, 2021 press release) at 3.

B. The Avatar Study (ANAVEX®2-73-RS-002)

While the U.S.-Based Phase 2 study was underway, Anavex commenced the Avatar study. Compl. ¶ 20. Information about the study was posted on ClinicalTrials.gov, including identified endpoints. Compl. ¶¶ 20-21.

When Anavex announced results of the Avatar study on February 1, 2022, it reported the results using an endpoint method referred to as RSBQ AUC. Compl. ¶ 43. In describing it, Dr. Missling noted known limitations with RSBQ as a stand-alone endpoint based on its propensity for error as a caregiver-measured score, and explained:

> The FDA hence recommended, and it's also provided in the guidelines from the FDA, and recommended specifically in these cases, because you don't have many choices of endpoints to pick from which have been validated for rare diseases like Rett Syndrome, to use instead the RSBQ with an anchor. That's called anchor-based responder method, which links the score from one clinical outcome assessment, the RSBQ in this case, with scores from a simple reference anchor, which is the outcome assessment with a clinically meaningful threshold, which is the CGI-I, and that facilitates the interpretation of what constitutes a meaningful within and between patient change in clinical outcome assessment. And so this RSBQ AUC was born.

Ex. 4 (Feb. 1, 2022 transcript) at 4. In explaining the choice of endpoint, the presentation slides reiterated that the FDA recommended an "anchor-based responder method," citing a guidance document issued by the agency. See Ex. 5 (presentation) at 4; Ex. 6 (FDA Guidance) at 29.[3] The slide identified RSBQ AUC as an example of such method.

[3] The slide presentation is referenced in the transcript and attached to a Form 8-K the Company filed with the SEC. When "the Complaint quotes and relies upon statements made in press releases

After releasing the Avatar results, Anavex issued a press release providing additional information regarding the change in endpoints. Compl. ¶ 56. A few days later, during an analyst call, Dr. Missling made clear that ClinicalTrials.gov should not be relied upon as the most updated source of information:

> And in regards to ClinicalTrials.gov, I would like to make, again, a statement here that the ClinicalTrials.gov is not what we refer to as company communication. It will be updated eventually. So I'd like you to – you to be aware of that. So the company communication is – has priority over ClinicalTrials.gov, but it will be updated when we have finalized the study outcome. And then we will also update the ClinicalTrials.gov. Right now, it might not be completely up to date. So I want to make sure people understand that.

Compl. ¶ 58; Ex. 7 (Feb. 9, 2022 transcript) at 8.

C. The Excellence Study (ANAVEX®2-73-RS-003)

The Excellence study commenced in late 2019 and was underway when the Avatar results were released. Compl. ¶ 24. The Company initially disclosed its intention to also use RSBQ AUC as an endpoint in Excellence. Compl. ¶ 53. This first occurred during the same February 1, 2022, conference call that revealed the Avatar results and the use of RSBQ AUC for that study. In response to a question regarding whether Excellence will also use RSBQ AUC, Dr. Missling responded by referring back to his earlier discussion about the FDA guidance to use an anchor-based methodology: "So that's right, the Excellence study will use the same endpoint because as just described, it is just the preference of the FDA." Ex. 4 (Feb. 1, 2022 transcript) at 13.

Partway through the Class Period, however, the Company announced that, after further consultation with the FDA, it would (unlike Avatar) not use RSBQ AUC. On February 7, 2023, during an earnings call, Dr. Missling had an exchange with an analyst in which he explicitly said

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and investor calls, the Court may properly consider the complete referenced press releases, the full transcripts of those calls, and any the SEC filings referenced and incorporated therein…." Koplyay v. Cirrus Logic, Inc., No. 13-cv-790 (CM), 2013 WL 6233908, *4 (S.D.N.Y. Dec. 2, 2013).

that the endpoint would *not* be RSBQ AUC, would thus differ from Avatar, and that instead the plan for the primary endpoint was RSBQ with CGI-I as key secondary endpoint:

> *Yun Zhong*
> Okay. And then switching to the Rett syndrome study, I believe the press release announcing over enrollment had the language that was the FDA's input. You are using the primary endpoint. So I wanted to confirm that the primary endpoint is RSBQ AUC, similar to or the same to the one used in the AVATAR study. And so has the FDA agreed that the AUC, the modified RSBQ scale can be an appropriate endpoint for Rett syndrome study?
>
> *Christopher U. Missling*
> We have it described in clinicaltrials.gov, and it was also never changed in clinicaltrials.gov for the EXCELLENCE study. It is - the RSBQ is primary endpoint and the CGI-I is key secondary endpoint. This is over the course of the trial.
>
> *Yun Zhong*
> Is that the same endpoint that was used in the AVATAR study?
>
> *Christopher U. Missling*
> It's slightly different. So it's actually the measurement over time from beginning to end of trial.
>
> *Yun Zhong*
> Not AUC?
>
> *Christopher U. Missling*
> Not AUC.
>
> *Yun Zhong*
> Not AUC.
>
> *Christopher U. Missling*
> Exactly, yes. Because the study is large enough that it can carry the signal by itself without AUC.
>
> *Yun Zhong*
> Okay, great.

Ex. 8 (Feb. 7, 2023 transcript) at 5-6.[4] Then, on June 6, 2023, the Company issued a press release that said:

[4] The Court can properly consider documents for the fact that information was publicly available and previously disclosed. See Staehr v. Hartford Fin. Servs. Grp., Inc., 547 F.3d 406, 425 (2d Cir.

> In communication with the FDA, the Company received the Agency's input on the study endpoints, which were utilized in this clinical study. The [RSBQ] total score and [CGI-I] score are co-primary endpoints in the statistical analysis plan with specified linear mixed-effects models for repeated measures (MMRM) as the primary analysis methods.

Ex. 9 (June 6, 2023 press release) at 2. Later press releases further confirmed these endpoints. Exs. 10 (June 12, 2023 press release) at 2; Ex. 11 (Aug. 8, 2023 press release) at 3.

II. Plaintiff's Alleged False Statements and Alleged "Corrective Disclosures"

The Complaint does not clearly set out what statements it alleges are false or misleading. In a section titled "Defendants' False and/or Misleading Statements and Omissions During the Class Period," Plaintiff cites the following:

- A June 21, 2021, press release that (Plaintiff alleges) announced data for the Avatar study and identified endpoints different than what was shown on ClinicalTrials.gov. Compl. ¶¶ 28-29. However, as explained further below and as the document itself makes clear, this press release related to the *U.S.-Based Phase 2 study*, not Avatar.
- A handful of disclosures, including a Form 8-K, prospectus supplement, Form 10-Q, Form S-3, prospectus, and earnings call statement. Compl. ¶¶ 30, 33, 35. Plaintiff does not identify anything in these statements that were false or materially misleading but alleges that none of them referenced any changes to the primary or secondary outcome measures for Avatar or Excellence. Compl. ¶¶ 31-33, 36.
- Two answers to analyst questions, Compl. ¶¶ 37-38, and two updates to ClinicalTrials.gov, Compl. ¶¶ 34, 40, though the Complaint does not identify if or how these were allegedly false or misleading.

2008); In re Sanofi Sec. Litig., 87 F. Supp. 3d 510, 539 n.13 (S.D.N.Y. 2015), aff'd sub nom. Tongue v. Sanofi, 816 F.3d 199 (2d Cir. 2016).

The Complaint also includes a section titled "Investors First Learn the Truth," in which Plaintiff recites various other statements by the Company or third parties from February 1, 2022, through January 2, 2024. Compl. ¶¶ 42-61.[5] He does not identify whether or how any of these statements is misleading. The closest he comes is to assert that a presentation filed on February 1, 2022, did not repeat a prior disclosure (Compl. ¶ 47) or explain why the Avatar endpoints were chosen (Compl. ¶ 49).

The Complaint also alleges broadly that Defendants' misled investors by "suggest[ing]" and/or "promis[ing]" that it would use particular endpoints, Compl. ¶ 61, and that in fact different endpoints were used in the Avatar and Excellence studies, as follows:

- As to the Avatar study, Plaintiff alleges that the true endpoint (RSBQ AUC) was revealed for the first time on February 1, 2022. Compl. ¶¶ 42-43.
- As to Excellence, he alleges that the incorrect endpoint (RSBQ AUC) was first communicated on February 1, 2022, and that the correct endpoints (RSBQ and CGI-I as co-primary endpoints) and measurement method (MMRM) were revealed on January 2, 2024, the day after the Class Period ended. Compl. ¶¶ 62-67.

On January 2, 2024, Anavex announced the results of the Excellence study. Compl. ¶ 62. The results were disappointing in that the study met one of the co-primary endpoints (RSBQ) but not the other (CGI-I). Compl. ¶ 63. Plaintiff alleges that analysts responded negatively to the announcement of the results and the Company's explanation of potential causes for those results

[5] The statements in this time period were all made within the class period for the action captioned *Huey v. Anavex Life Sciences Corporation*, No. 24-cv-1910, which Mr. Downing moved (unsuccessfully) to have consolidated with this action and moved (unsuccessfully) to be appointed lead plaintiff. In denying those motions, the Court made clear that if Mr. Downing continued with the present case, he could not represent a class of persons who are also members of the class in *Huey*. It is therefore unclear to what extent (if any) Mr. Downing can pursue liability based on statements made after February 1, 2022.

(Compl. ¶ 70), but Plaintiff does not allege that any analyst commented or reacted in any way with respect to the choice of endpoints.[6] Plaintiff alleges that shares of Anavex stock tumbled after the Company released the Excellence results. Compl. ¶ 71.

III. Procedural History

Prior to this lawsuit being filed, another Anavex investor, Jonathan Blum, filed a lawsuit (No. 1:24-cv-1910-CM) with similar allegations covering a shorter class period: February 1, 2022, through January 2, 2024 (i.e., the period from the release of the Avatar results until the release of the Excellence results). Counsel for the plaintiff in that case issued the required PSLRA notice, beginning the 60-day period for class members to seek to be named lead plaintiff. On May 8, 2024, five days before that PSLRA notice period expired, the Plaintiff filed this lawsuit. On May 13, 2024, Mr. Downing filed a motion for consolidation with the *Blum* case and also sought to be appointed lead plaintiff.

The Court held a hearing on June 13, 2024, in which it denied the motion to consolidate, denied Mr. Downing's motion to be appointed lead plaintiff in the previously-named *Blum* action, and appointed Quintessa Huey as the lead plaintiff in that case (now captioned *Huey v. Anavex Life Sciences Corp.*, No. 1:24-cv-1910-CM). In its ruling, the Court explained that Mr. Downing could proceed with his separate case, but that any class he represents could not include members of the class in the *Huey* case. No. 24-cv-1910, ECF No. 32 at 6:6-8.

Mr. Downing elected not to amend the Complaint. No motion for lead plaintiff has been filed in the present action and no lead plaintiff has been appointed.

[6] Plaintiff also makes passing criticisms of the way in which Excellence data was presented on January 2, 2024, but none of these statements is alleged to be misleading – this is the alleged *corrective* disclosure.

STANDARD OF REVIEW

"To survive dismissal, the plaintiff must provide the grounds upon which his claim rests through factual allegations sufficient 'to raise a right to relief above the speculative level.'" ATSI, 493 F.3d at 98 (citation omitted). "Allegations that are conclusory or unsupported by factual assertions are insufficient." Id. at 99. "A securities fraud complaint must also meet the heightened pleading standards of [Rule] 9(b) and the [PSLRA]." Kleinman v. Elan Corp., plc, 706 F.3d 145, 152 (2d Cir. 2013). The "circumstances constituting fraud" must be "state[d] with particularity," including the reasons *why* a statement is misleading. Id.

ARGUMENT

As shown below, the Complaint fails to establish nearly all of the required elements of a Section 10(b) and Rule 10b-5 claim, i.e., misstatements or omissions of material fact, made with scienter, in connection with the purchase or sale of securities, upon which the plaintiff relied, and proximate causation of injury. Koplyay, 2013 WL 6233908, at *4 (citing Lentell v. Merrill Lynch & Co., Inc., 396 F.3d 161, 172 (2d Cir. 2005)). Much of the claim is also time-barred. As such, both Count I and Count II (which is derivative of Count I) should be dismissed.

I. Plaintiff Utterly Fails to Meet the High Burden Established to Plead Scienter in Securities Fraud Cases.

The Complaint is striking for the almost non-existent effort undertaken to plead scienter. A plaintiff must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind," i.e., an "intention 'to deceive, manipulate, or defraud.'" Tellabs, Inc. v. Makor Issues & Rts., Ltd., 551 U.S. 308, 313-14 (2007) (citations omitted); see also ECA & Local 134 IBEW Joint Pension Tr. of Chicago v. JP Morgan Chase Co., 553 F.3d 187, 198 (2d Cir. 2009). It amounts to deliberate, illegal behavior or conduct constituting "an extreme departure from the standards of ordinary care to the extent that the danger was either

known to the defendant or so obvious that the defendant must have been aware of it." In re Lululemon Sec. Litig., 14 F. Supp. 3d 553, 573 (S.D.N.Y. 2014), aff'd, 604 F. App'x 62 (2d Cir. 2015) (citation omitted). In assessing whether a plaintiff has adequately pled scienter, the "court must consider plausible, nonculpable explanations for the defendant's conduct." Tellabs, 551 U.S. at 324. For an inference of scienter to be strong, "a reasonable person [must] deem [it] cogent and *at least as compelling* as any opposing inference one could draw from the facts alleged." Id. (emphasis added).

The Complaint contains a *single paragraph* regarding scienter, and it consists entirely of conclusory statements that merely parrot the two avenues for pleading scienter in the Second Circuit. Compl. ¶ 72. See ATSI, 493 F.3d at 99 (describing motive and opportunity or strong circumstantial evidence of conscious misbehavior or recklessness). This is clearly insufficient to establish scienter in a securities fraud case.

First, Plaintiff does not allege any particular motive, i.e., no allegation that Defendants "benefitted in some concrete and personal way from the purported fraud." Novak v. Kasaks, 216 F.3d 300, 307-08 (2d Cir. 2000). A simple recitation that there was "motive and opportunity" does not satisfy the pleading burden.

Next, Plaintiff similarly does not allege anything to support his conclusory allegation that Defendants "had actual knowledge of the misleading nature of the statements they made or acted in reckless disregard of the true information known to them at the time." Compl. ¶ 72; see also Compl. ¶¶ 81, 89. The standard to plead conscious misbehavior or recklessness is high (and even greater absent allegations of motive). Kalnit v. Eichler, 264 F.3d 131, 143 (2d Cir. 2001). A plaintiff "must *specifically* identify the reports or statements" from which defendants learned facts contrary to the public representations. Novak, 216 F.3d at 309. A plaintiff's "failure to do so is

sufficient to end the inquiry." Shetty v. Trivago N.V., 796 F. App'x 31, 35 (2d Cir. 2019) (summary order); see also Koplyay, 2013 WL 6233908, at *7 (dismissing complaint that "never makes reference to any internal reports, statements by confidential witnesses, or other specific facts showing that Defendants had access to" the allegedly undisclosed contrary data).

Plaintiff does not cite any internal document, describe any internal meeting, or quote a single witness (let alone a credible one). Instead, he relies only on his own conclusory statements and naked inference that Dr. Missling *must have known* certain asserted facts due to his corporate position, an allegation routinely dismissed as insufficient. Compl. ¶¶ 18, 72, 81, 89. See City of Brockton Ret. Sys. v. Shaw Grp. Inc., 540 F. Supp. 2d 464, 473 (S.D.N.Y. 2008) (McMahon, J.) (rejecting general allegation that defendants must have known accounting improprieties due to involvement in daily operations, absent factual allegations supporting inference of knowledge such as "access to particular, identified internal reports that would have alerted them"); Okla. Firefighters Pension & Ret. Sys. v. Student Loan Corp., 951 F. Supp. 2d 479, 497-98 (S.D.N.Y. 2013).

In fact, the Complaint does not even allege that, *at the time any statement about endpoints was made*, Defendants knew that the endpoints would be different than what was disclosed. Instead, Plaintiff alleges merely that the endpoints changed after the Company "suggested" or "promised" that they would not. Compl. ¶ 61; see also Compl. ¶ 7 ("Anavex used different outcomes"). But a breach of promise does not amount to a securities fraud claim. Mills v. Polar Molecular Corp., 12 F.3d 1170, 1176 (2d Cir. 1993).

In contrast to Plaintiff's rote recitation of the scienter standards and conclusory assertions, the alleged facts instead present a more compelling and supported non-fraudulent alternative: that Anavex, based on FDA guidance, decided to anchor CGI-I to RSBQ, and did so using the RSBQ

AUC measure. Anavex also intended to use that endpoint for Excellence as it communicated publicly, but partway through the Class Period Anavex met further with the FDA and, based in part on those discussions, decided to instead use RSBQ and CGI-I as co-primary endpoints. Anavex disclosed this after the change was decided, on multiple occasions during the Class Period. When Anavex announced somewhat disappointing Excellence results in January 2024, the negative market reaction was due to that, not the (already disclosed) endpoints. This is all consistent with the Company's disclosures.

II. The Intra-Class Period Disclosure of the Excellence Endpoints Negates Plaintiff's Claims of False or Misleading Statements

The several, clear intra-Class Period disclosures about the actual Excellence endpoints entirely undercut Plaintiff's case. His theory is that Defendants knowingly did not reveal the Excellence endpoints until the end of the Class Period. Compl. ¶ 9. That is demonstrably false. On February 7, 2023, Defendants explicitly disclosed that (unlike Avatar) the Excellence endpoint would not involve RSBQ AUC. Ex. 8 at 5-6. On June 6, 2023, the Company further disclosed that the Excellence study would have co-primary endpoints of RSBQ and CGI-I, and would use the MMRM method to analyze results. Ex. 9 at 2. This was repeated on June 12, 2023, and August 8, 2023. Exs. 10 at 2; Ex. 11 at 3.

Nothing regarding a change of endpoints was disclosed on January 2, 2024. The only new information released that day was the Excellence study results. Thus, there can be no liability, as the Complaint fails to allege omission of material fact that was not disclosed until after the Class Period. See In re Progress Energy, Inc., 371 F. Supp. 2d 548, 552 (S.D.N.Y. 2005) ("[I]t is indisputable that there can be no omission where the allegedly omitted facts are disclosed."); Okla. Firefighters, 951 F. Supp. 2d at 500 ("[D]efendants disclosed precisely the type of information plaintiffs claim was withheld."); Bettis v. Aixtron SE, No. 16 CIV. 00025 (CM), 2016 WL

7468194, at *11 (S.D.N.Y. Dec. 20, 2016) ("[O]n several occasions, [the company] made exactly the disclosures that Plaintiff claims were withheld from investors."); Ganino v. Citizens Utils. Co., 228 F.3d 154, 167 (2d Cir. 2000) ("[A] misrepresentation is immaterial if the information is already known to the market because the misrepresentation cannot then defraud the market.").

III. Loss Causation Is Negated by the Intra-Class Period Disclosures of Endpoints

The prior disclosures of the actual study endpoints also negate loss causation.

First, as to Avatar, Plaintiff admits that the actual endpoint of RSBQ AUC was disclosed on February 1, 2022. Compl. ¶¶ 42-43. None of the market movement on January 2, 2024, could properly be ascribed to the disclosure of the Avatar endpoint. In re New Energy Sys. Sec. Litig., 66 F. Supp. 3d 401, 405 (S.D.N.Y. 2014) ("[T]o establish loss causation, 'a plaintiff must allege ... that the *subject* of the fraudulent statement or omission was the cause of the actual loss suffered.'" (citation omitted)). Although Plaintiff alleges the market declined on the day the Avatar results were released, Compl. ¶ 54, his loss causation allegations exclusively relate to January 2, 2024. Compl. ¶¶ 73-76.

Second, as to Excellence, any decline in stock price on January 2, 2024, cannot plausibly be understood as attributable to disclosure of anything with respect to endpoints. As explained in the prior section, the endpoints were previously disclosed and the announcement on January 2, 2024, did not reveal anything about endpoints that was unknown up to that point. See Okla. Firefighters, 951 F. Supp. 2d at 503 (citing Lentell, 396 F.3d at 173); Fort Worth Emps. Ret. Fund v. Biovail Corp., 615 F. Supp. 2d 218, 229 (S.D.N.Y. 2009) ("The all-but-inevitable decline in the price of Biovail's stock price following the company's announcement that the FDA had not approved the [drug application] was caused by the agency's failure to approve the drug—not by any 'corrective' disclosure of some prior untruth."); see also In re Signet Jewelers Ltd. Sec. Litig.,

No. 16-cv-6728 (CM), 2019 WL 3001084, at *19 (S.D.N.Y. July 10, 2019) ("[C]ourts are required to cut off the class period on the date of a statement or event that cures the market.").

IV. The Complaint Does Not Allege Any False or Misleading Statement or Omission of Material Fact with the Required Particularity

Plaintiff's haphazard recitation of various statements made by Defendants during the Class Period does not satisfy the heightened pleading standards that apply to securities fraud cases. "Untrue statements must be identified and, if applicable, so must the omitted facts that are 'necessary in order to make the statements made, in the light of the circumstances in which they were made, not misleading.'" Kleinman, 706 F.3d at 152 (quoting 15 U.S.C. § 78u-4). "The Second Circuit has repeatedly stated that plaintiffs must do more than simply assert that a statement is false—'they must demonstrate with specificity why that is so.'" In re Lululemon, 14 F. Supp. 3d at 571 (quoting Rombach v. Chang, 355 F.3d 164, 174 (2d Cir. 2004)); see also In re AstraZeneca plc Sec. Litig., No. 21-cv-722, 2022 WL 4133258 (S.D.N.Y. Sept. 12, 2022) ("[T]he PSLRA obligates the plaintiff to 'demonstrate with specificity why and how' each statement is materially false or misleading." (citation omitted)), aff'd sub nom. Nandkumar v. AstraZeneca PLC, No. 22-2704-CV, 2023 WL 3477164 (2d Cir. May 16, 2023).

A. The Complaint Fails to Adequately Identify and Explain the Allegedly False or Misleading Statements

It is unclear from the Complaint what statements (or parts thereof) are even alleged to be misleading. As noted above, Plaintiff recites a series of statements without explaining why they are misleading. Plaintiff merely says that the statements did not specifically disclose changes to endpoints. "Such allegations do not specify why and how each statement is misleading because they do not specify what understanding each statement left investors, and how that understanding was inconsistent with alleged omissions." In re AstraZeneca, 2022 WL 4133258, at *6. To plead an actionable omission, a plaintiff must describe with particularity what statement was made

materially misleading due to the omitted fact, including *why* it was misleading. See Polar Int'l Brokerage Corp. v. Reeve, 108 F. Supp. 2d 225, 241 (S.D.N.Y. 2000); Lululemon, 14 F. Supp. 3d at 571; see also Gamm v. Sanderson Farms, Inc., 944 F.3d 455, 463 (2d Cir. 2019) ("Under Rule 9(b) and the PSLRA, the circumstances of a fraud include 'the basis' for that contention."). Plaintiff has not done that here. Even more crucially, Plaintiff has not alleged any facts to support that, *at the time the statement was made*, the endpoints had in fact changed. A statement of future intent is not false unless the speaker did not honestly believe it at the time. See In re Lululemon, 14 F. Supp. 3d at 571.

B. Several of the Statements At Issue Do Not Involve Any Cognizable Fraud

Plaintiff measures the start of his Class Period based on a June 21, 2021, press release that he describes as where "Anavex announced 'convincing biomarker correlating efficacy data' for the AVATAR study." Compl. ¶ 28. In addition to not adequately alleging what about this was false or misleading, this allegation suffers from an even more fundamental flaw: *this press release has nothing to do with Avatar, and instead relates to an entirely different study*. Even a cursory review of the press release makes clear that it relates to the U.S.-Based Phase 2 study. Ex. 3 (June 21, 2021 press release). Indeed, it says it in the first paragraph. The press release also explicitly distinguishes Avatar and Excellence as "two *other* ongoing late-stage placebo-controlled clinical studies." Id. (emphasis added). Accordingly, even had Plaintiff alleged something misleading about this press release, it would not present a plausible claim.

The Complaint also faults the February 1, 2022, disclosure for two things: it "failed to note" other information the Company previously disclosed (Compl. ¶ 47) and it failed to explain why the Company decided to use CGI-I as an anchor despite previously saying it "[did]n't want to overemphasize" that score (Compl. ¶ 49). Neither criticism supports a claim for securities fraud. The first criticism attacks Defendants for not repeating again a disclosure the Company had already

made. Plaintiff therefore admits the information was already disclosed. In re Progress Energy, Inc., 371 F. Supp. 2d 548, 552 (S.D.N.Y. 2005) ("[I]t is indisputable that there can be no omission where the allegedly omitted facts are disclosed."). As to the second item, Plaintiff fails to allege *why* it was misleading for the Company not to address Plaintiff's own subjective criticism of the data presentation. It also ignores the lengthy passages in the analyst call transcript where the Company explained why it was using the RSBQ AUC metric anchored to CGI-I. See Ex. 4 (Feb. 1 2022 transcript) at 4.

C. Any Remaining Criticisms of the Choice of Endpoints Do Not State a Claim

To the extent the Complaint can otherwise be read as making general criticisms of Anavex's choice of endpoints or design of the clinical trial, such quibbles do not state a securities fraud claim. Numerous cases reject claims against biopharmaceutical companies that second-guess how data is presented. See, e.g., Kleinman, 706 F.3d at 154–55 (dismissing a complaint that argued that the company's changing of measures to present data in a different format must have been misleading, explaining defendants had no obligation to present results in any particular format); In re Sanofi-Aventis Sec. Litig., 774 F. Supp. 2d 549, 567 (S.D.N.Y.2011) ("Plaintiffs cannot premise a fraud claim upon a mere disagreement with how Sanofi chose to interpret the results."); Abely v. Aeterna Zentaris Inc., No. 12 CIV. 4711, 2013 WL 2399869, at *2-3, 6-9 (S.D.N.Y. May 29, 2013) ("The Second Circuit and other tribunals have concluded that the securities laws do not recognize a fraud claim premised on criticisms of a drug trial's methodology, so long as the methodology was not misleadingly described to investors.").

V. Claims as to Avatar Are Time-Barred and Divorced from the Corrective Disclosure

All of Plaintiff's claims fail for the reasons explained above, i.e., the utter absence of scienter allegations, earlier intra-Class Period disclosure, and failure to plead with particularity. Plaintiff's allegations as to the Avatar study fail for the additional reason that they are time-barred.

A claim under Section 10(b) and Rule 10b-5 must be filed within two years after discovery of the facts constituting the violation. 28 U.S.C. § 1658(b). The limitations period "begins to run once the plaintiff actually discovered or a reasonably diligent plaintiff would have 'discover[ed] the facts constituting the violation'—whichever comes first." Merck & Co. v. Reynolds, 559 U.S. 633 (2010) (quoting 28 U.S.C § 1658(b)(1)). The same limitations period applies to Count II under Section 20(a), which is derivative of Count I. In re MBIA Inc., No. 05-cv-3514, 2007 WL 473708, at *9 (S.D.N.Y. Feb. 14, 2007).

As the Complaint makes clear, the final Avatar endpoints were publicly disclosed on February 1, 2022. Compl. ¶¶ 6, 42-46. At that time, analysts "critiqued" and "chided" the Company for the changes and lowered the target on Anavex shares. Compl. ¶¶ 6, 50-52. The announcement of the endpoint change was accompanied by negative market reaction. Compl. ¶ 54. In other words, *all* of the allegedly concealed information was fully disclosed as of February 1, 2022, and that is when Plaintiff allegedly experienced a loss associated with the Avatar-related disclosure. Any claim would have fully accrued at that point. Plaintiff filed the Complaint on May 8, 2024—two years, three months, and one week later. Accordingly, claims regarding the alleged failure to disclose the change of endpoints as to the Avatar study are time-barred.[7]

[7] Indeed, Plaintiff's decision to start his Class Period in June 2021 appears derived entirely from a desire to show the largest market loss so as to be appointed lead plaintiff in the *Huey* matter. Looking only within the statute of limitations period, Mr. Downing has *no losses* using a last-in-first-out analysis. He purchased and sold 1,000 shares at a realized *gain* and then—less than six weeks before the end of the Class Period and *well after* disclosure of the Excellence endpoints—he purchased another 1,000 shares. See ECF No. 15-2. Per Plaintiff's own calculations, this results in a net gain (inclusive of the recognized value for his retained shares) of $2,355.99. Id.

CONCLUSION

For all of the reasons outlined above, the Court should dismiss the Complaint.

Date: August 23, 2024

Respectfully submitted,

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